

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

**KERRY LANGSTAFF, et al**

Petitioners,

v.

**ALLEN A. MITCHELL, M.D.,  
SAMUEL M. LESKO, M.D., and  
TRUSTEES OF BOSTON UNIVERSITY**

Respondents.

§ **Civil Action No. 04-MBD**

§

§ **Related Civil Action:**

§ **United States District Court for the  
§ Northern District of California, San  
§ Jose Division**

§ **Civil Action No. 03-CV-01116**

§ **KERRY LANGSTAFF, et al vs.**

§ **MCNEIL CONSUMER &**

§ **SPECIALITY**

§ **PHARMACEUTICALS, et al**

§

§

**PETITIONERS' MEMORANDUM IN SUPPORT OF  
PETITIONERS' MOTION TO COMPEL**

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Petitioners, by and through their attorney of record, and files this Memorandum in Support of Petitioners' Motion to Compel. Petitioners bring forth this Motion to Compel from service of subpoenas duces tecum upon the Custodian of Records for Dr. Allen A. Mitchell and the Custodian of Records for Slone Epidemiology Center (hereinafter "Boston University"). Both custodians are affiliated with and represented by Boston University. Petitioners seek to compel production in regards to crucial documents, which go to the heart of Petitioners' suit against McNeil Consumer & Speciality Pharmaceuticals (hereinafter "McNeil") and Johnson & Johnson filed in the United States District Court for the Northern District of California. Petitioners seek relief from this Court as subpoenas were issued by this Court and Boston University is within the province of the Court's jurisdiction. *See* Fed. R. Civ. P. 45(b)(2).

**I. BACKGROUND**

This is a pharmaceutical products liability case involving the injury and untimely death of 8-year-old Kaitlyn Sierra Langstaff from Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN) caused by an adverse reaction to Children's Motrin. Defendants McNeil and Johnson

& Johnson relied upon the results from the Boston University Fever Study to support the approval of the over the counter marketing of Children's Motrin. This study was the critical safety study that McNeil used to claim the safety of ibuprofen in the treatment of fever in children in the U.S. Plaintiffs seek to obtain documents from Respondents. Petitioners seek to compel the following requests:

Request #4 - All presentations, slides, lectures or related documents that were presented to the FDA on behalf of McNeil Consumer Healthcare or Wyeth Consumer Healthcare regarding ibuprofen.

Request #8 - Copies of all research studies, including drafts of or final manuscripts sponsored by McNeil Consumer Healthcare or Wyeth Consumer Healthcare, whether published in peer-reviewed journals or unpublished studies, on the subjects of adverse skin reactions by adults or children from ibuprofen; SJS or TEN caused by or associated with ibuprofen; renal toxicity of ibuprofen; gender differences of adverse reactions to ibuprofen.

Request #9 - All drug safety committee, data and monitoring committee or other committee reports in the Boston Fever Study that reviewed the safety of ibuprofen that discuss any adverse event or reaction associated with ibuprofen, including, but not limited to: skin conditions, such as rash, erythema multiforme, SJS, TEN, or renal failure.

Request #10 - All contracts or agreements for the employment of Boston University or Boston University Medical Center or Slone Epidemiology Unit, School of Public Health, Boston University School of Medicine to conduct the clinical trial that was known as the Boston Fever Study, including all correspondence, contract, memorandums, agreements, payments, reports or other documents that dealt with the Boston Fever Study.

Request #12 - All agreements, contracts, consulting agreements, proof of payments, 1099 forms, checks, or documents between Samuel Lesko, M.D. or Allen A. Mitchell, M.D. and

McNeil Consumer Healthcare or Wyeth Consumer Healthcare or Johnson & Johnson that reflect payment as a clinical investigator in the Boston Fever Study.

Request #17 – A list of all 1700 physicians who participated in the Boston Fever Study along with their addresses and phone numbers.

Request #18 – All printouts of every e-mail between Samuel Lesko, M.D. or Allen Mitchell, M.D. or the Slone Epidemiology Unit of Boston University and McNeil Consumer Healthcare or Wyeth Consumer Healthcare or their agents, employees or designated representatives concerning the evaluation of the safety and efficacy of ibuprofen in children.

Request #19 – All documents that detail the financial support, grants, donations, or money paid to the Slone Epidemiology Unit, Boston University School of Medicine or its affiliated institutions, or Boston University by McNeil Consumer Healthcare or Wyeth Consumer Healthcare for the last 10 years.

Request #23 – All expert reports generated by Dr. Samuel Lesko, Dr. Allen Mitchell or any staff member of Boston University for McNeil Consumer Healthcare or Wyeth Consumer Healthcare regarding ibuprofen.

Request #25 – All minutes of meetings, or reports or unpublished documents from any scientific or medical advisory committee participating in the Boston Fever Study.

## **II. ARGUMENT**

### **A. Boston University's Objections Were Untimely**

A party may obtain documents from a nonparty by subpoena. Fed. R. Civ. P. 34(e) and 45(a)(1)(c). The nonparty may serve objections to inspection or copying of any or all of the designated items within 14 days of service of the subpoena, so long as the time specified for production in the subpoena is more than 14 days from the date of service. Fed. R. Civ. P. 45(c)(2)(B). In the matter at hand Petitioners served its subpoena duces tecum on November 4,

2003. *See* Exhibit A. The production date was set twenty days later on November 24, 2003. *See id.* Thus, Boston University was required to serve any objections by Tuesday, November 18, 2003. *See* Fed. R. Civ. P. 45(c)(2)(B). However, Boston University failed to comply within 14 days of service as required. *Id.* Boston University did not make any objections to Petitioner's subpoena duces tecum until November 19, 2003. *See* Exhibit B. Accordingly, Boston University has waived all of its objections by not complying with Rule 45. *United States ex rel. Schwartz v. TRW, Inc.*, 211 F.R.D. 388, 392 (C.D. Cal. 2002) *citing In re DG Acquisition Co.*, 151 F.3d 75, 81 (2<sup>nd</sup> Cir. 1998) (Holding that all objections, including those made for privilege, were waived); *In re Motorsports Merchandise Antitrust Litigation*, 186 F.R.D. 344, 349 (W.D. Va. 1999) *citing Concord Boat Corp., et al., v. Brunswick Corp.*, 169 F.R.D. 44, 48 (S.D.N.Y.1996); *see Semtek International, Inc. v. Merkurij Ltd.*, 1996 WL 238538 at 2 (N.D.N.Y.1996); *Deal v. Lutheran Hospital & Homes*, 127 F.R.D. 166, 168 (D. Alaska 1989); *see also Wang v. Hsu*, 919 F.2d 130, 131 (10th Cir.1990); *Creative Gifts, Inc., v. UFO*, 183 F.R.D. 568, 570 (D.N.M.1998); *Wright v. Montgomery County*, 1999 WL 80275 at 3-4 (E.D.Pa. Feb. 3, 1999); *Alexander v. FBI*, 1998 WL 292083 at 6 (D.D.C. May 28, 1998). Accordingly, Petitioners' Motion to Compel should be granted.

#### **B. Boston University's Objections Are Without Merit**

Even if the Court were to entertain Boston University's non-compliant objections to Petitioners' subpoena, Petitioners Motion to Compel should still be granted. Rule 45 establishes the same broad scope of discovery to a non-party that exists to the parties involved in the litigation. *United States ex rel. Schwartz v. TRW, Inc.*, 211 F.R.D. 388, 392 (C.D. Cal. 2002). Rule 34 applies to parties involved in the litigation with requests for production governed by Rule 26. *Id.* Rule 26 "is liberally interpreted to permit wide-ranging discovery of information even though the information may not be admissible at the trial." *Id. citing Jones v. Commander, Kansas Army Ammunitions Plant*, 147 F.R.D. 248, 250 (D. Kan. 1993). Relevance for discovery

purposes is given very broad meaning. *Allen v. Howmedica Leibinger, Inc.*, 190 F.R.D. 518, 521 (W.D.Tenn.1999).

Boston University makes numerous objections to the subpoena contending that Petitioner's discovery against McNeil in the underlying suit makes these requests burdensome and repetitive. Petitioners' have been involved in what amounts to a game of litigation pinball, as McNeil and Boston University repeatedly point to each other as the source of various materials. *See* Exhibit C. Petitioners simply seek to obtain relevant discovery. In particular, McNeil claims to have no correspondence documents in its possession relating to the Boston Fever Study. *See* Exhibits C and D. This contention is made to Petitioners even though McNeil served on the committee for serious adverse events. Thus, any material could represent an admission against interest. In regards to the clinical data from the advisory committee meetings, McNeil has produced vague documentation, which consistently mentions other meetings, which have not been produced to Petitioner. *Id.* McNeil asserts that it does not possess these minutes, but Boston University does. *Id.* Petitioners' merely seek to discover the truth and be able to prepare for their case with all relevant documents. Boston University has produced no evidence and simply made conclusory statements regarding its burden. *See Ihussey v. State Farm Lloyds Ins. Co.*, 216 F.R.D. 591, 595 (E.D. Tex. 2003). It is, however, an appropriate avenue for Petitioners to seek documentation. *See* Fed. R. Civ. P. 34(c) and 45(a)(1)(C). A Court should only not honor a subpoena if "it is palpable that the evidence sought can have no possible bearing upon the issues." *See Hercules Powder Co. v. Rohm & Hass Co.*, 3 F.R.D. 302, 304 (D.Del.1943). The subpoena duces tecum served on Boston University clearly seeks documentation that bears directly on Petitioners law suit against McNeil. *See* Exhibit C. Petitioners acknowledge that its subpoena constitutes some burden on Boston University. Accordingly, Petitioners are willing to reduce the burden on Boston University by going to its storage facilities to review.

Boston University asserts that Petitioners seek discovery already produced by McNeil. However, Petitioners would not seek discovery, nor spend the time and resources required, from a

third-party if Petitioners had obtained the requested discovery from McNeil. Petitioners have exhausted all documentation that McNeil claims to possess. *See* Exhibits C and D. Petitioners also do not seek to breach the confidentiality of the study participants. Petitioners have no interest in the identity of study participants, but merely the results and reactions that happened to participants. Accordingly, Petitioners cannot fathom how compliance with the subpoenas would quell efforts to attract volunteers for future research studies. Petitioners would also like to note that they are simply individuals who have suffered through a tremendous tragedy. Petitioners are involved in litigation stemming from the death of a young girl. In determining if disclosure would be harmful, the Court must consider "not the injury that would be caused by public disclosure, but the injury that would result from disclosure under an appropriate protective order." *Coca Cola Bottling Co. v. The Coca Cola Co.*, 107 F.R.D. 288, 293 (D.Del.1985). Disclosure to a competitor is presumed to be more harmful than disclosure to a non-competitor. *Id.* Thus, Petitioners have no interest in "trade secrets" or "commercial information" which are the basis of Rule 45(c)(3)(B). Petitioners merely seek to discover the knowledge, which was had, or should have been had, of the dangers of skin afflictions from the ingestion of ibuprofen and whether or not there was concealment of these dangers or bias in the studies. *See Hussey*, 216 F.R.D. at 594. With this in mind, it is clear to see Petitioners are entitled to documentation not produced to the FDA and manuscripts other than published studies, which are the same items that Petitioners contend concealed the dangers that resulted in the death of Kaitlyn Sierra Langstaff.


### III. CONCLUSION

Petitioners are entitled to discovery from nonparties, such as Boston University. *See* Fed. R. Civ. P. 34(c) and 45(a)(1)(C). Boston University failed to object in the required time period, and the objections made are not compelling. Accordingly, Petitioners Motion to Compel should be granted in full.

(415) 433-4440  
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**ATTORNEYS FOR PETITIONER**


**CERTIFICATE OF SERVICE**

I certify that the foregoing Motion to Compel and Memorandum in Support was served on Boston University and all counsel of record via facsimile and U.S. Mail on the \_\_\_\_ day of May, 2004.

  
Edward Paul Coady


**CERTIFICATE OF CONFERENCE**

I certify that counsel for Petitioners and counsel for Custodian of Records for Dr. Allen A. Mitchell and the Custodian of Records for Slone Epidemiology Center have discussed this matter via telephone on or around April 20, 2004. No resolution was reached regarding the matters contained therein.

  
Edward Paul Coady

**REQUEST FOR ORAL ARGUMENT**

I certify that Petitioners wish to be heard by the Court regarding this matter as expeditiously as possible and believe that oral argument would assist the Court.

  
Edward Paul Coady